

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

PATTY KREGLOW,

CASE NO. 3:23 CV 2173

Plaintiff,

v.

JUDGE JAMES R. KNEPP II

SANOFI-AVENTIS U.S. LLC,

Defendant.

**MEMORANDUM OPINION AND
ORDER**

INTRODUCTION

Currently pending before the Court is Plaintiff Patty Kreglow's Motion for Leave to Amend Complaint (Doc. 22) and Memorandum in Support (Doc. 23). Defendant Sanofi-Aventis U.S. LLC opposes (Doc. 25), and Plaintiff replies (Doc. 26). For the reasons discussed below, Plaintiff's motion is denied.

BACKGROUND

This case is one of many originally filed in a multidistrict litigation ("MDL") in the United States District Court for the Eastern District of Louisiana. *See In re: Taxotere (Docetaxel) Products Liability Litigation*, MDL. No. 16-2740. The cases involved claims that Defendant and others that manufactured and distributed the chemotherapy drug Taxotere (or its generic version, docetaxel), which plaintiffs assert caused Permanent Chemotherapy Induced Alopecia. *See generally* Doc. 9 (Transfer Order summarizing MDL proceedings).

Procedural History

As is typical in MDL proceedings, the MDL court required the MDL plaintiffs to file a Master Complaint, applicable to all plaintiffs, and individual short form complaints. *See id.* at 74.

The individual short form complaints incorporated the general allegations in the Master Complaint and contained space for a plaintiff to identify which causes of action from the Master Complaint the individual plaintiff asserted, as well as identify any additional theories or causes of action. *See Doc. 1 (Plaintiff's short form complaint).*

On March 31, 2017, the MDL plaintiffs filed a Master Complaint, applicable to all plaintiffs. *See id.* at 74. The MDL plaintiffs then filed a First Amended Complaint. *See id.* Defendants moved to dismiss the First Amended Complaint, and the MDL court granted the motion in part; it dismissed plaintiffs' claims for strict product liability for misrepresentation and breach of express warranty. *Id.* at 74-75. As to these claims, the MDL Court recognized the "limitations and restrictions" associated with asserting fraud allegations in a master complaint, and therefore stated that "specific allegations, particularly with respect to any allegations of fraud, should be perfected within the short form complaints filed in the individual member cases." (Doc. 25-1, at 3-4) (Transcript of August 30, 2017 MDL Court proceeding). The Court gave plaintiffs two weeks for such amendments. (Doc. 8-2, at 121).

In September 2018, the MDL plaintiffs filed a Second Amended Master Complaint, which is identical to the First Amended Master Complaint, but added two defendants. *See id.* at 150. This Second Amended Complaint remains the operative pleading. (Doc. 9, at 75).

As relevant here, the Second Amended Master Complaint describes the injury as "Permanent Chemotherapy Induced Alopecia, which is defined as an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy." (Doc. 8-4, at 377-78).

In December 2019, the MDL plaintiffs moved for leave to file a Third Amended Master Complaint. *See Doc. 8-4, at 1425* (order denying motion). Therein, the MDL plaintiffs sought an amendment stating:

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed “persistent” six months beyond the completion of chemotherapy.

(Doc. 8-4, at 458). The MDL court denied the motion; it explained:

The parties and the Court have been operating under Plaintiffs’ original definition of their alleged injury since Plaintiffs adopted it in their original master complaint filed on March 31, 2017. Magistrate Judge North used the definition in resolving certain discovery disputes. For example, when Plaintiffs requested a 30(b)(6) deposition (presumably the first of several) and asked Sanofi to produce a representative who could discuss reports of “persistent alopecia” with Taxotere, Sanofi objected to the broad nature of this request. Judge North ruled that “persistent alopecia” meant alopecia remaining six months after chemotherapy. This Court also adopted Plaintiffs’ definition in its summary judgment rulings on statute of limitations issues. Indeed, Plaintiffs’ own expert, Dr. Laura Plunkett, adopted this definition in her expert report, writing that the medical literature generally defines irreversible alopecia as “hair loss that is still seen six months after treatment has ended.” The Fifth Circuit has held that a defendant is unduly prejudiced by granting leave to amend if the changes to the complaint would require additional discovery and the defendant to prepare a different defense. If the Court were to allow Plaintiffs to amend at this late stage, this would negate a significant amount of the work that has been done in this MDL. Defendants would undoubtedly want to revise certain expert reports and conduct supplemental depositions, and certain rulings from the Court would be mooted.

Id. at 1427-28. The Court concluded that it was “apparent that the main reason” for seeking amendment was “to save cases that are otherwise subject to dismissal for being filed too late” and found that permitting such an amendment “would cause serious prejudice to Defendants.” *Id.* at 1428-29; *see also id.* at 1429 (“Presumably, Plaintiffs made an informed decision to define their injury the way they originally did. The Court will not allow Plaintiffs at this point in the MDL to backtrack on that decision.”).

Following this denial, three MDL plaintiffs¹ moved to revise the definition of Permanent Chemotherapy Induced Alopecia in their individual short form complaints. (Doc. 8-4, at 1431-32). The MDL court denied these individual motions for the same reasons it denied the motion to amend the Master Complaint. *Id.* at 1433-34.

On May 11, 2020, the MDL Court issued Pretrial Order (“PTO”) 105, in response to “many Plaintiffs” who had “begun amending . . . their individual Short Form Complaints in response to this Court’s rulings on recent motions seeking to amend pleadings as they relate to the statute of limitations.” (Doc. 8-2, at 167). PTO 105 permitted plaintiffs to “amend their complaints to add factual allegations regarding particularized facts individual and specific to each Plaintiff’s medical care and treatment and/or that Plaintiff’s communications with medical professionals.” *Id.* Following a stipulated extension, the deadline for such amendment was January 15, 2021. *Id.* at 168-69. The parties also stipulated that plaintiffs “agree[d] not to seek leave to amend . . . to add or include any allegations that are inconsistent with PTO 105 of this Court’s Orders addressing motions to amend [short form complaints], including any allegations that have been previously disallowed by the Court.” *Id.* at 169. They stipulated that if there was a dispute as to whether a proposed amendment was inconsistent in such a manner, “the Defendant may place the case on a call docket, designating the allegations it believes violates PTO 105 or any of the Court’s orders on language appropriate for an amendment, for Plaintiffs to show cause why Plaintiff’s proposed allegations should not be stricken.” *Id.* at 170. This stipulation also provided that “[i]f a Defendant seeks dismissal of any case based on a statute of limitations, it agrees that it will not argue waiver based on any Plaintiff’s refraining from amending her [short form complaint] to include allegations inconsistent with PTO 105.” *Id.* at 169.

1. These were the three plaintiffs the MDL Court had selected to proceed with discovery in connection with the third bellwether trial. (Doc. 8-4, at 1431-32).

Plaintiff filed her amended short form complaint in the MDL Court on December 5, 2017. *See* Doc. 1. As to the nature and extent of her injury, Plaintiff described “Permanent Alopecia, total baldness, with only a very thin layer of fine hair or fuzz that grows.” *Id.* at 4. She endorsed the Master Complaint’s claims for strict products liability – failure to warn, negligence, negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, and fraud and deceit. *Id.* She did not add anything additional under a question for “Other: Plaintiff(s) may assert the additional theories and/or State Causes of Action against Defendant(s) identified by selecting “Other” and setting forth such claims below.” *Id.* Plaintiff did not add any additional factual detail and never amended nor sought to amend this short form complaint.

In November 2023, Plaintiff’s case was transferred to this Court for further proceedings. *See* Doc. 9. In the Order transferring Plaintiff’s case to this Court, the MDL Court stated: “All deadlines for Plaintiffs to amend their individual complaints without leave of court have passed.” (Doc. 9, at 76). This Court held a case management conference on January 9, 2024, at which time it set a deadline for Plaintiff to file a motion for leave to amend.

Allegations in Proposed Amended Complaint

Plaintiff seeks leave to amend “to comply with Ohio pleading requirements and allege case specific facts.” (Doc. 23, at 2). She asserts that she “filed her complaint, by way of short form with text boxes and check boxes for certain case-specific information” but “[t]he short form complaint did not provide Plaintiff with a text box inviting allegations into any case-specific facts regarding her knowledge of the link between Taxotere and the Plaintiff’s permanent hair loss injury.” *Id.* As Plaintiff’s reply brief acknowledges, there are three areas of proposed amendment. *See* Doc. 26.

First, the proposed amended complaint seeks to, *inter alia*, alter the definition of the injury as follows:

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed “persistent” six months beyond the completion of chemotherapy.

(Doc. 22-1, at ¶ 102).

Second, it adds a claim for Non-conformance with Representations under the Ohio Products Liability Act, Ohio Revised Code § 2307.77. *Id.* at ¶¶ 180-87. In this claim, Plaintiff asserts Defendants “misrepresented facts as set forth herein concerning the character or quality of Taxotere”, which were material, and that “Plaintiff and/or her healthcare providers reasonably relied” on those purported misrepresentations. *Id.* at ¶¶ 183, 185.

Third, the proposed amended complaint seeks to add a section entitled “Plaintiff Specific Factual Allegations.” *Id.* at ¶¶ 157-66. In this section, Plaintiff asserts her prescribing oncologist informed her “that hair loss from chemotherapy would be temporary in nature” and she was “never informed that her use of Taxotere may result in permanent hair loss.” *Id.* at ¶ 159-60. She further asserts that had she been made aware of the risk of permanent hair loss, “she would have asked for a different treatment option.” *Id.* at ¶ 161. Further, she asserts she “did not learn that Taxotere causes permanent hair loss until she saw a legal advertisement in 2016”, then “sought legal counsel to investigate her potential claim, and filed a lawsuit against Sanofi in December of 2017, well within Ohio’s two-year statute of limitations.” *Id.* at ¶¶ 164-65.

DISCUSSION

Plaintiff requests leave to amend “to comply with state-specific pleadings requirements and add case-specific facts”. (Doc. 22, at 1). She asserts that because the focus of the MDL was

“on general discovery and completion of a bellwether process”, no amendments had been previously allowed “beyond amending the short form complaint which contained text boxes and check boxes for minimal/form case-specific allegations.” *Id.* at 1-2. Defendant contends Plaintiff’s motion should be denied because amendment is both impermissible (as barred by the law-of-the-case doctrine) and untimely and unjustified at this stage of the case. It contends Plaintiff’s amendments seek to undo previous rulings by the MDL court, and further, that any amendment would be futile. For the reasons discussed below, the Court denies Plaintiff’s motion.

Revisions to Definition of Permanent Chemotherapy Induced Alopecia

Plaintiff’s motion contains no discussion of the above-described procedural history regarding proposed amendments in the MDL court to the definition of “Permanent Chemotherapy Induced Alopecia.” *See* Doc. 23. In reply, Plaintiff asserts the amendment “addresses vagueness and inaccurate science surrounding one paragraph in the master pleadings” (Doc. 26, at 2) and does not “‘redefine’ the injury”, but rather makes it “consistent with medical science”, citing two expert reports. (Doc. 26, at 2-3). Defendant contends any such amendment is barred by the law-of-the-case doctrine, and that Plaintiff has not demonstrated the MDL court’s ruling was “clearly erroneous or manifestly unjust” to overcome such a bar.

As recently set forth by another judge of this Court:

Under the law-of-the-case doctrine, “a decision on an issue made by a court at one stage of a case should be given effect in successive stages of the same litigation.” *United States v. Todd*, 920 F.2d 399, 403 (6th Cir. 1990) (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816, (1988)). The doctrine “promotes judicial efficiency by prohibiting parties from indefinitely relitigating the same issue that a court resolved in an earlier part of the case.” *Samons v. National Mines Corp.*, 25 F.4th 455, 463 (6th Cir 2022).

A court can revisit a prior decision, but only “(1) where substantially different evidence is raised on subsequent trial; (2) where a subsequent contrary view of the law is decided by the controlling authority; or (3) where a decision is clearly erroneous and would work manifest injustice.” *Hanover Ins. Co. v. Am. Eng’g*

Co., 105 F.3d 306, 312 (6th Cir. 1997). This is true in the MDL context as well. The Sixth Circuit has held that “as a practical matter” the transferee court “ought . . . to accord considerable deference to the judgment of the transferor court.” *In re Upjohn Co. Antibiotic Cleocin Prods. Liab. Litig.*, 664 F.2d 114, 120 (6th Cir. 1981).

Antalocy v. Sanofi US Servs., Inc., 2024 WL 1328570, at *4 (N.D. Ohio); *see also* Wright & Miller, 15 FED. PRAC. & PROC. JURIS. § 3867 (4th ed.) (Law of the Case Doctrine and the Effect of Transfer and Remand on Choice of Law) (“Indeed, exceptions to the law of the case principle should be especially rare in these circumstances, because refusal to follow the previous ruling would result in the sort of piecemeal decision making that MDL centralization is intended to avoid.”).

Here, the MDL court rejected a nearly identical amendment regarding the definition of Permanent Chemotherapy Induced Alopecia to the one Plaintiff seeks to add.² But even in her reply brief, Plaintiff does not acknowledge that the MDL court denied an identical requested amendment; rather, she seeks to reargue the issue. The Court finds Plaintiff has not demonstrated the MDL court’s determination was clearly erroneous or manifestly unjust. Consistent with other courts within the Sixth Circuit and around the country to address the issue, this Court sees no reason to revisit the MDL court’s determination on this issue. *See Antalocy v. Sanofi US Servs.*,

2. Any difference between the previously proposed (and rejected) language, and the currently proposed language is not a substantively meaningful one. The Proposed Third Amended Master Complaint stated: “There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs” (Doc. 8-4, at 458), while Plaintiff’s currently proposed amendment eliminates the underlined language (Doc. 22-1, at 24).

Inc., 2024 WL 1328570, at *4-5 (N.D. Ohio)³; *Jackson v. Sanofi-Aventis U.S., LLC*, 2024 U.S. Dist. LEXIS 48896, at *16-17 (M.D. Tenn.).⁴

Non-Conformance With Representation Claim

In her Reply, Plaintiff states she “can agree that this proposed additional cause of action be withdrawn consistent with the MDL Court’s ruling on Count II of the master pleadings.” (Doc. 26, at 4). The Court therefore need not address this proposed amendment.

Case Specific Facts Regarding Fraud and Timeliness

As to Plaintiff’s request to amend to add case-specific allegations, she argues “there has never been a case-specific scheduling order or deadline to amend” (Doc. 23, at 4) and that “[t]he short form complaint did not provide Plaintiff with a text box inviting allegations on any case-specific facts regarding her knowledge of the link between Taxotere and the Plaintiff’s permanent hair loss injury” (Doc. 23, at 2). She contends PTO 105 allowed for only limited amendments and “[i]ndeed, as the Stipulation notes, plaintiffs disagreed with the limitations the MDL Court placed on amendments in PTO 105.” (Doc. 26, at 5).

Two federal rules govern pleading amendments. First, Rule 15 provides that “[t]he court should freely give leave” to amend a pleading “when justice so requires.” Fed. R. Civ. P. 15(a)(2). Second, Rule 16 requires the district court to enter a scheduling order that includes a deadline for amending pleadings, and it requires a district court modify a scheduling order “only for good cause” Fed. R. Civ. P. 16(b)(3)(A), (b)(4). Consequently, notwithstanding Rule 15’s

3. Plaintiff’s reply brief both acknowledges and attaches the recent ruling by another judge of this Court in *Antalocy* denying leave to amend, but “respectfully submits that reasonable minds can differ on the appropriate outcome.” (Doc. 26, at 1).
4. Defendants have attached a document containing more than fifteen rulings denying similar requests to amend. *See* Doc. 25-2. Notably, Plaintiff has not cited a single case where a plaintiff who, after return to the district court from this MDL court, has been permitted to amend their complaint.

directive to freely give leave to amend, a party seeking leave to amend after a scheduling order's deadline must meet Rule 16's good-cause standard for the district court to amend the scheduling order. *Leary v. Daeschner*, 349 F.3d 888, 909 (6th Cir. 2003); *Commerce Benefits Grp. Inc. v. McKesson Corp.*, 326 F. App'x 369, 376 (6th Cir. 2009) ("Once the scheduling order's deadline to amend the complaint passes, . . . a plaintiff *first* must show good cause under Rule 16(b) for failure earlier to seek leave to amend and the district court must evaluate prejudice to the nonmoving party before a court will [even] consider whether amendment is proper under Rule 15(a).") (internal quotation marks and citation omitted) (emphasis added). Parties "can demonstrate 'good cause' for their failure to comply with the original schedule [] by showing that despite their diligence they could not meet the original deadline." *Leary*, 349 F.3d at 907; *see also Commerce Benefits Grp., Inc.* 326 F. App'x at 376 (denying a motion to amend after a scheduling order deadline because the movant failed to "adequately explain its delay").

The parties first dispute which rule applies here. Defendant contends that because PTO 105 set a deadline for amendment, Rule 16's heightened "good cause" standard applies, rather than Rule 15's more lenient standard. (Doc. 25, at 15). Defendant contends, however, that under either standard, Plaintiff should not be permitted to amend. Plaintiff does not address Rule 16 (seemingly in reliance on her statement that "there was never a case-specific order setting a deadline for pleading amendments, and the time to seek such amendment has not passed"), and contends amendment is permitted under Rule 15.

PTO 105 was specifically directed at amendments related to the statute of limitations and set a deadline for MDL plaintiffs to "amend their complaints to add factual allegations regarding particularized facts individual and specific to each Plaintiff's medical care and treatment and/or that Plaintiff's communications with medical professionals." (Doc. 8-2, at 167). The allegations

Plaintiff seeks to add in the “Plaintiff Specific Factual Allegations” section of the proposed amended complaint (Doc. 22-1, at 38-39), are precisely the type of allegations contemplated by PTO 105. Indeed, Plaintiff’s own description confirms this: “the additional allegations, both general and case-specific, lay out facts that support both the timeliness of [Plaintiff’s] claims and the actions of [Defendant] to conceal from the public its knowledge of the risk and complaints from users of Taxotere about permanent hair loss.” (Doc. 26, at 5).

Upon review, the Court agrees with Defendant (as well as other courts to confront this issue) that PTO 105 is a scheduling order applicable to Plaintiff’s case, and thus, Rule 16’s standard – not Rule 15’s – governs amendment here. *See Antalocy*, 2024 WL 1328570, at *6; *Jackson*, 2024 U.S. Dist. LEXIS 48896, at *16. Plaintiff must therefore demonstrate “good cause” to amend. A court primarily measures “good cause” under Rule 16 by considering two factors: (1) “the moving party’s diligence in attempting to meet the case management order’s requirements,” and (2) “possible prejudice to the party opposing the modification.” *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625 (6th Cir. 2002). Both factors weigh against permitting amendment here.

First, Plaintiff provides little explanation for her failure to amend (or even seek to amend) within the timeframe previously provided. *See Jackson*, 2024 U.S. Dist. LEXIS 48896, at *23 (“Plaintiffs did not move to amend within the time frame set by the MDL Court and have made no argument as to why they could not have done so, except to say that they thought this deadline did not apply to them. The Court is not persuaded.”). Plaintiff cites the parties’ stipulation to PTO 105, which noted that Defendant “would not argue untimeliness or waiver of amendment if MDL plaintiffs chose not to challenge the limitation of PTO by filing a contested amendment beyond what PTO 105 would allow”. (Doc. 26, at 5). But this Court agrees with *Antalocy* that

“since [Defendant] is not ‘seek[ing] dismissal of [this] case based on a statute of limitations,’ that clause is not at issue here.” 2024 WL 1328570, at *6.

Second, Plaintiff contends she “always considered that she would have an opportunity to further conform her allegations to the facts of the case and the law of the jurisdiction in which it is being litigated” and that “there are numerous case-specific facts still to be discovered in this case” that did not happen in the MDL prior to remand, and that “the defense appears to be playing a ‘gotcha’ game freezing in time and holding plaintiffs to a complaint that is out of date.” (Doc. 26, at 5). She further argues that amendment will not prejudice Defendant as it “has not yet been required to file a case-specific answer, discovery has not begun, and Plaintiff has yet to give her deposition testimony.” (Doc. 23, at 4). But like many other courts to consider this issue, the Court finds these arguments unpersuasive. Defendant filed a Master Answer in the MDL (Doc. 8-4, at 246-341), which the MDL court “deemed to have answered all cases pending in, filed in, or subsequently transferred to the MDL.” (Doc. 8-2, at 16). Further, the transfer order states the purpose of the MDL was to “eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary” (Doc. 9, at 1-2); it additionally noted that because “all general fact and expert discovery has been completed in the MDL, the courts receiving these cases need not be concerned with facilitating general expert, corporate, and third-party discovery.” (Doc. 9, at 116). Thus, the Court finds Plaintiff has not demonstrated diligence in seeking to amend.

As to the prejudice prong of the “good cause” analysis, as *Antalocy* explained: “Many of the MDL court’s pretrial rulings concerned the statute of limitations, an issue *Antalocy*’s proposed amendments would directly affect . . . Allowing *Antalocy* to amend her complaint at this late stage would undo much of the MDL court’s work and, in the process, prejudice

[Defendant].” 2024 WL 1328570, at *7; *see also Jackson*, 2024 U.S. Dist. LEXIS 48896, at *30-31 (finding Defendants would be prejudiced by amendment at this stage and that “allowing Plaintiffs to amend at this stage would nullify the work of the MDL Court”). Because the Court finds Plaintiff has not demonstrated good cause for amendment, her motion for leave to amend is denied.

Finally, even if the Court were to apply Rule 15’s standard rather than Rule 16’s, it would still deny the request to amend based on undue delay and unfair prejudice. *See* MDL Order Denying Motion for Leave to Amend, Doc. 8-4, at 1428 (“If the Court were to allow Plaintiffs to amend at this late stage, this would negate a significant amount of the work that has been done in this MDL. Defendants would undoubtedly want to revise certain expert reports and conduct supplemental depositions, and certain rulings from the Court would be mooted.”); *Jackson*, 2024 U.S. Dist. LEXIS 48896, at *23-32 (finding similar proposed amendment would fail under Rule 15 standard in addition to under Rule 16).

CONCLUSION

For the foregoing reasons, good cause appearing, it is

ORDERED that Plaintiff’s Motion for Leave to Amend (Doc. 22) be, and the same hereby is, DENIED.

s/ James R. Knepp II
UNITED STATES DISTRICT JUDGE